



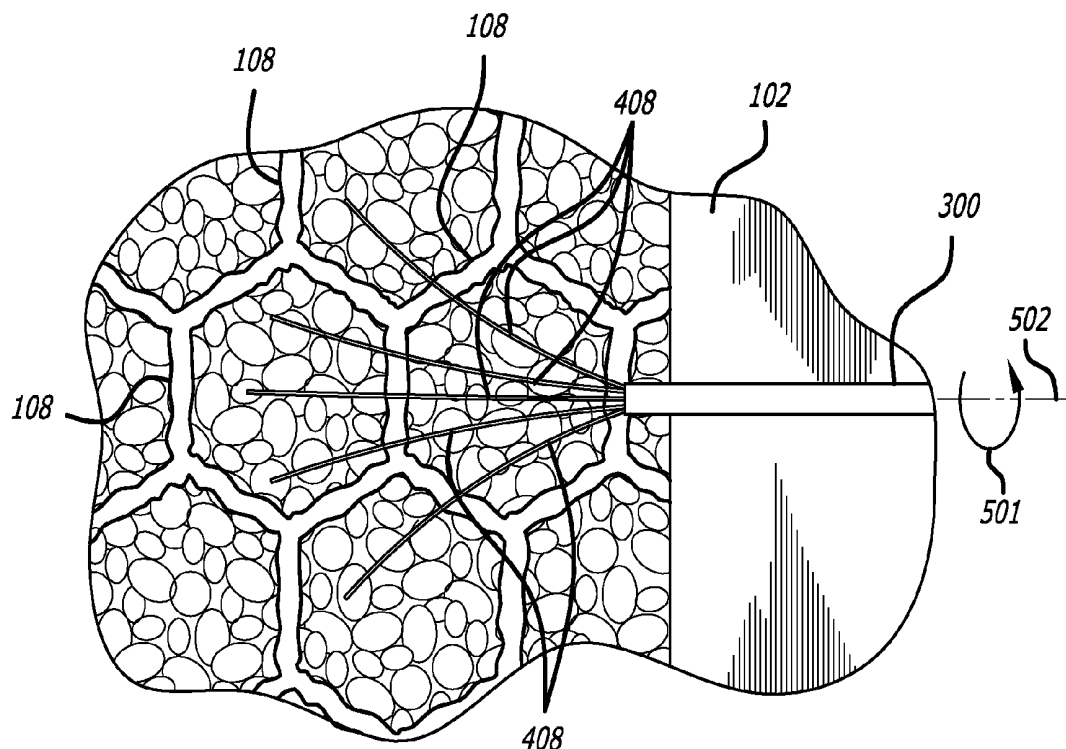
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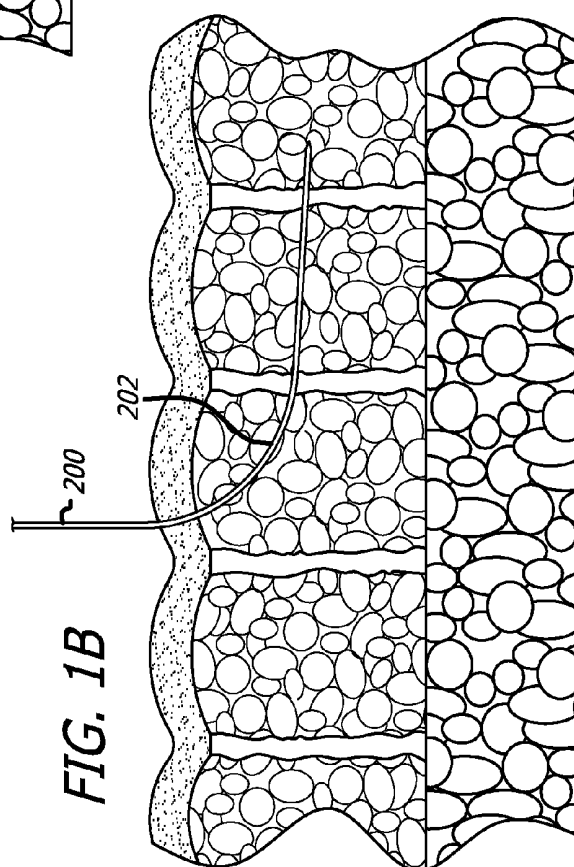
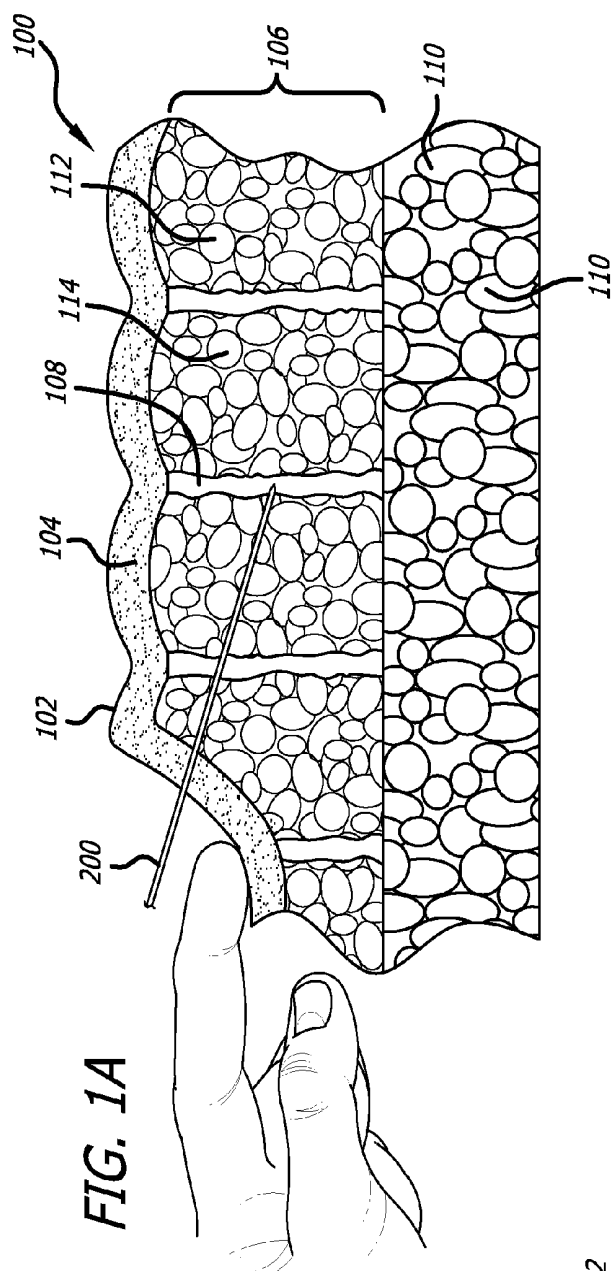
(19) **United States**(12) **Patent Application Publication**
Chomas et al.(10) **Pub. No.: US 2009/0326439 A1**(43) **Pub. Date: Dec. 31, 2009**(54) **HIGH PRESSURE PRE-BURST FOR
IMPROVED FLUID DELIVERY****Publication Classification**(75) Inventors: **James E. Chomas**, Boulder, CO
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filed on Sep. 5, 2006, Continuation-in-part of applica-
tion No. 11/334,794, filed on Jan. 17, 2006, now Pat.
No. 7,588,547.(57) **ABSTRACT**

A needle with multiple injection ports is used in connection with a high-pressure injection system to infuse a treatment solution into a treatment area below the dermis of the skin. The needle has multiple tines that extend outwardly from the injection ports while inside the treatment area to disrupt tissue in the treatment area and to create multiple pathways of infusion. The tines are withdrawn and the needle is partially withdrawn, and solution is injected from the needle into the treatment area at high pressure to infuse the tissue within the treatment area. The burst, infusion, and a treatment such as an energy or third solution may be interleaved and repeated multiple times.





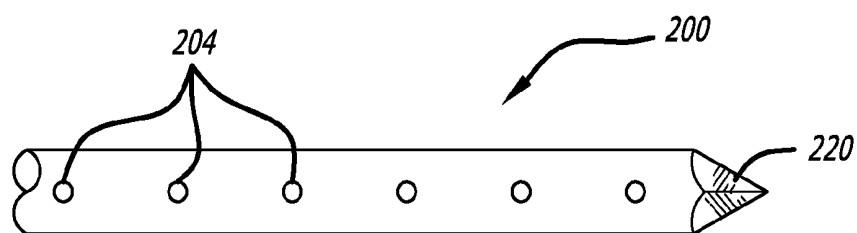


FIG. 2A

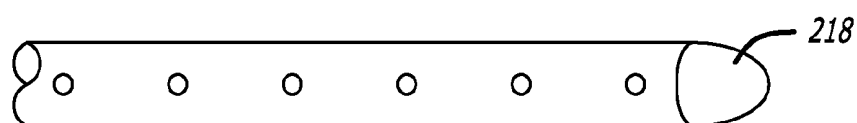


FIG. 2B

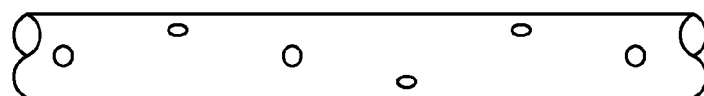


FIG. 2C

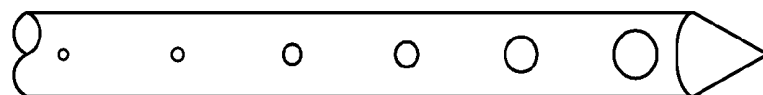


FIG. 2D

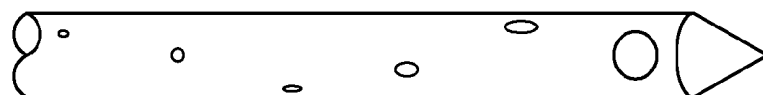


FIG. 2E

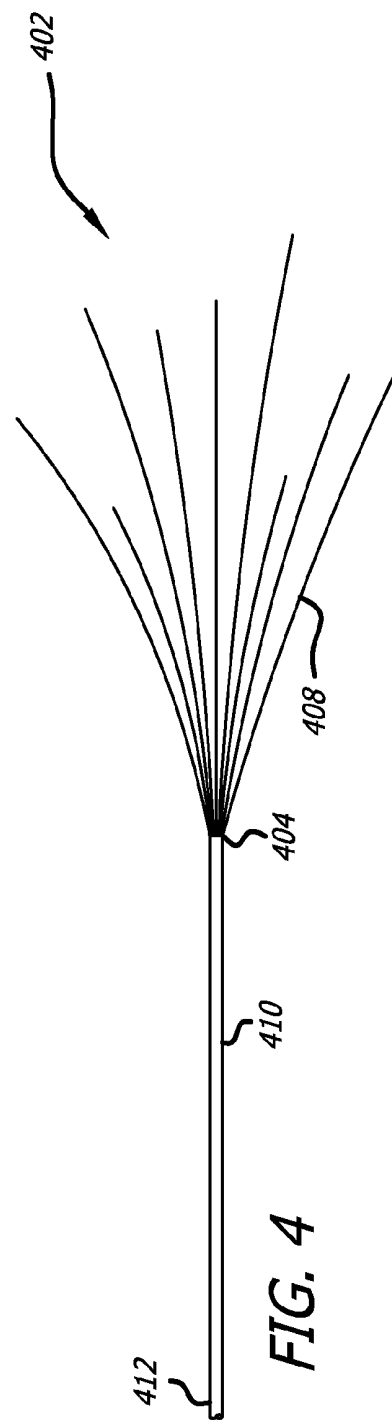
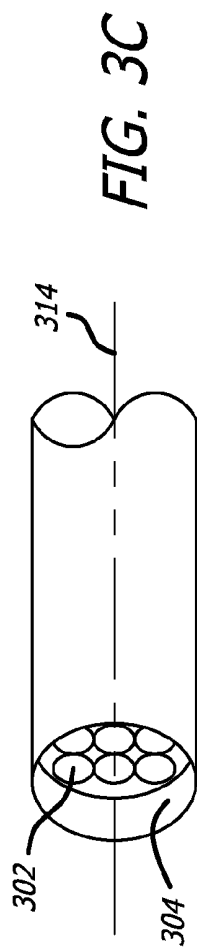
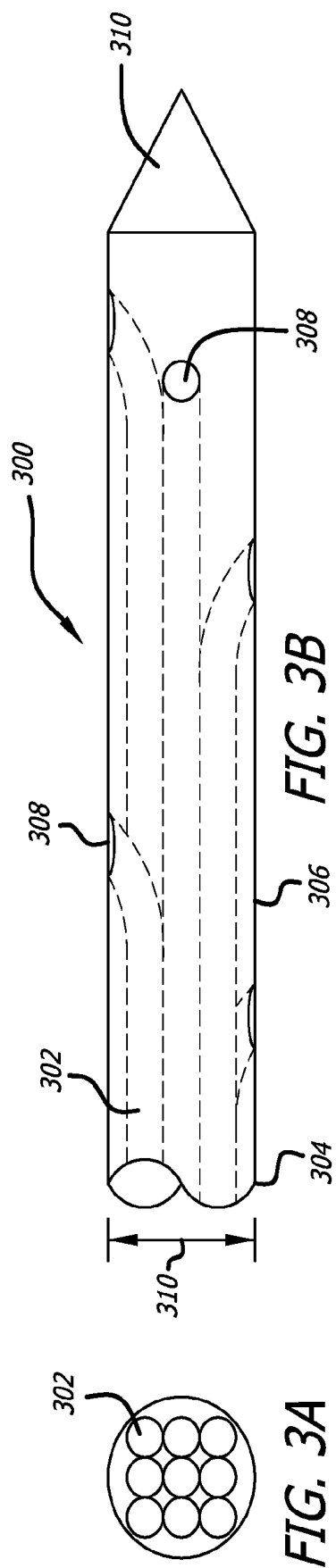


FIG. 6A

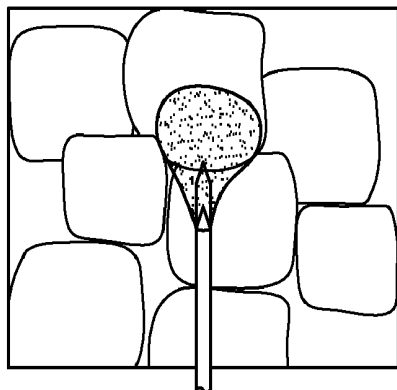


FIG. 6B

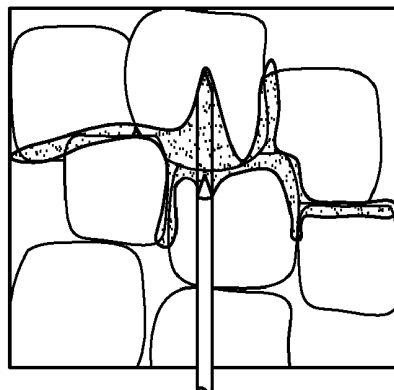


FIG. 7A

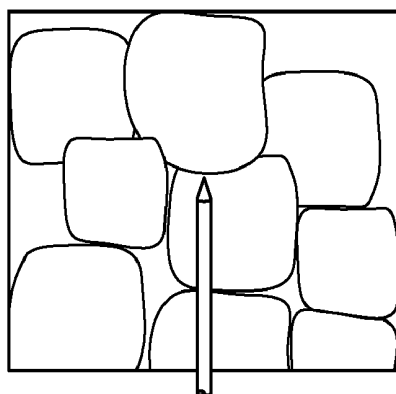


FIG. 7B

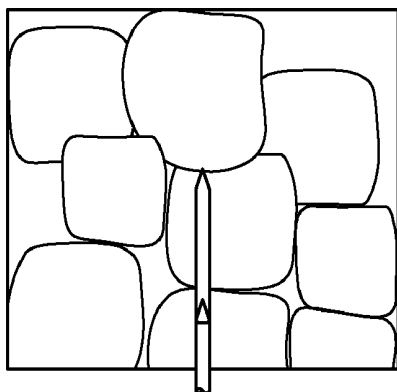


FIG. 7C

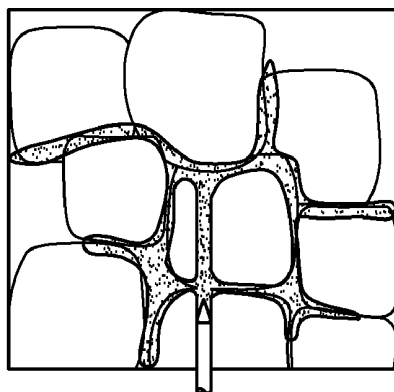


FIG. 8A

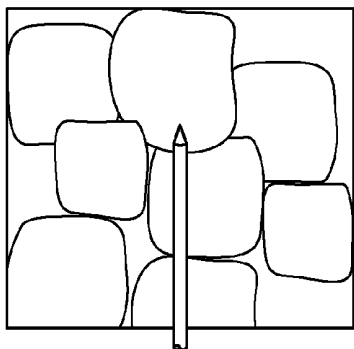


FIG. 8B

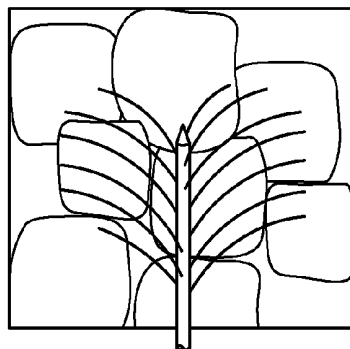


FIG. 8C

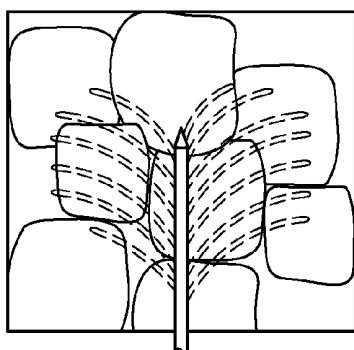


FIG. 8D

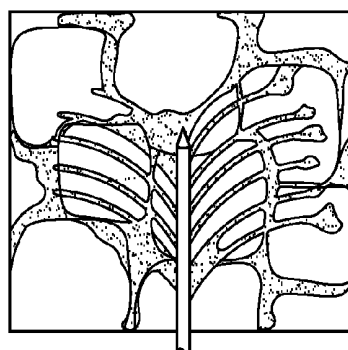


FIG. 9

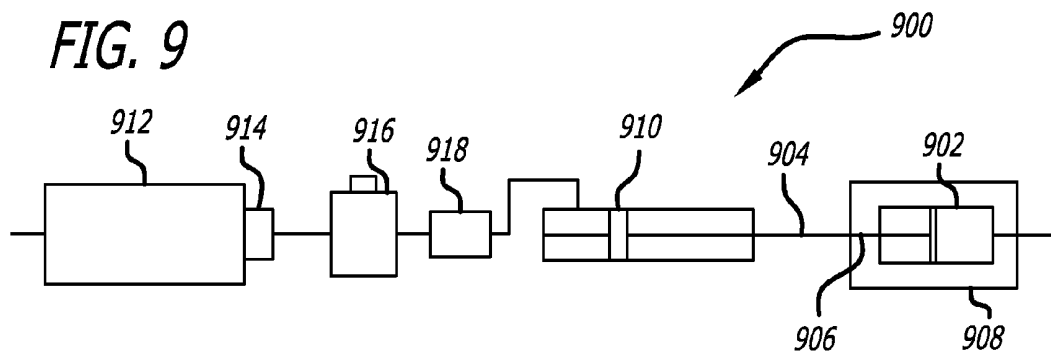


FIG. 10A

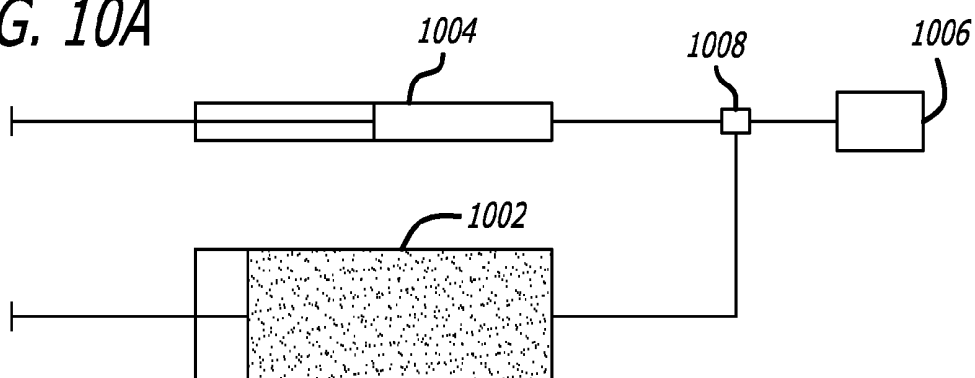


FIG. 10B

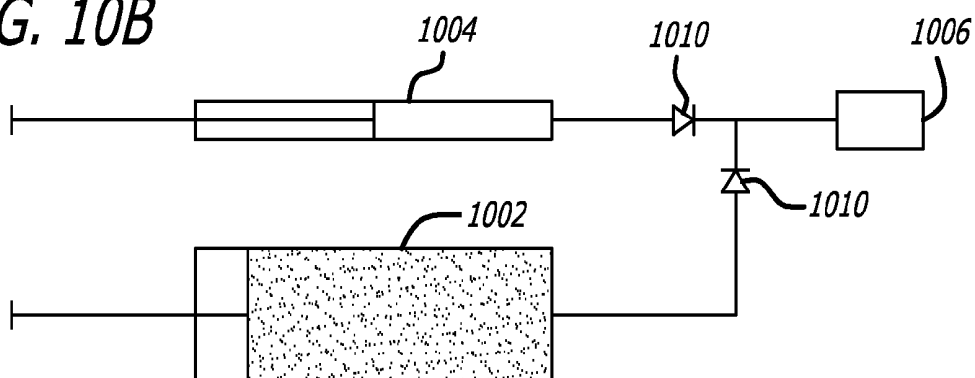


FIG. 10C

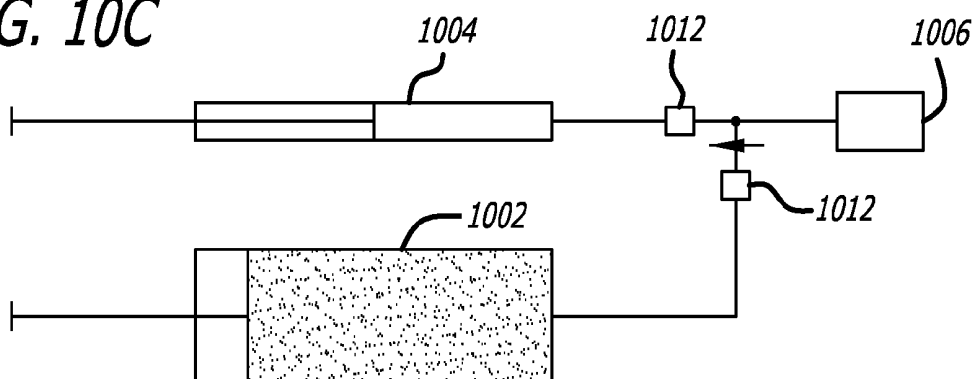


FIG. 11A

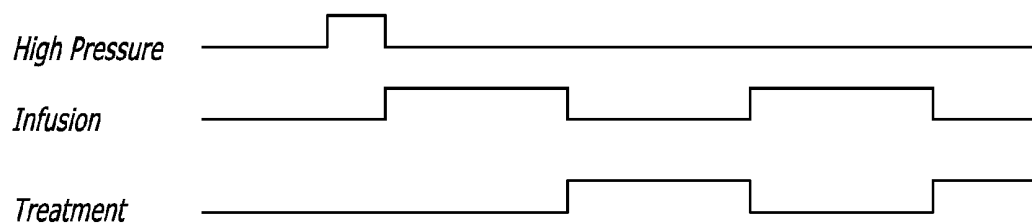
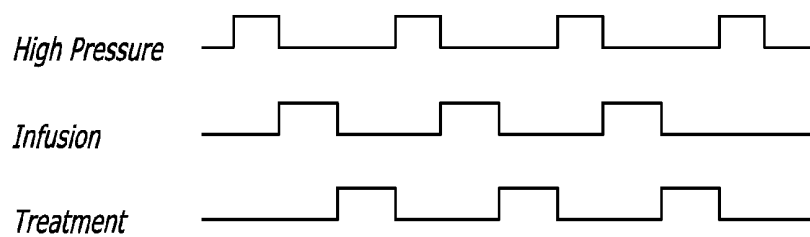


FIG. 11B



HIGH PRESSURE PRE-BURST FOR IMPROVED FLUID DELIVERY

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part and claims priority from U.S. application Ser. No. 11/515,634, filed Sep. 5, 2006, and from U.S. application Ser. No. 11/334,794, filed Jan. 17, 2006, now U.S. Pat. No. 7,588,547, both of which are incorporated by reference in their entirety.

BACKGROUND

[0002] It has been discovered that the prominence of fibrous septae within the immediate subdermal layers restricts fluid permeability between respective chambers of fat cells. Although these fibrous structures do not necessarily isolate neighboring chambers, localized pockets are nevertheless created by the structures and fluid flow is substantially restricted to the chamber proximate the injection site. It has been further discovered that these structures are not generally impermeable to a fluid. Accordingly, it has been discovered that a substantial amount of pressure utilizing the device and method herein described will penetrate neighboring chambers and beyond and the fat cells therein to provide enhancement of therapeutic treatments.

SUMMARY OF THE INVENTION

[0003] According to a first embodiment, a device is disclosed, including a needle having at least two holes along a side of the needle, wherein the holes increase in diameter toward a distal end of the needle. The holes at the distal end of the needle are, in some aspects, larger in area A_i than those near a proximal end, such that $A_3 > A_2 > A_1$ where $\sum A_i \geq A_{needle}$, wherein A_{needle} is the cross-sectional area of the needle. In one aspect, a sum of areas of the holes is greater than the area of a needle surface proximal to the holes. The holes may be staggered or linearly disposed along a side of the needle, and the device may be made of a rigid or flexible material.

[0004] In one aspect, a plurality of elongated elements are disposed within the needle and capable of movement from a first retracted configuration within the needle to a second extended configuration outside the needle from each respective hole, wherein the distal ends of the elongated elements are farther apart from each other in the extended configuration than in the retracted configuration. At least one of the plurality of elongated elements may be an electrode, and each electrode may be at least partially electrically insulated from the other elongated elements. In some embodiments the plurality of elongated elements is one of a cutting element or a harmonic scalpel.

[0005] The needle may comprise a series of interior capillaries originating at a point proximal an end of a needle shaft, wherein each interior capillary traverses a length of the shaft to terminate at a respective output port. Each of the plurality of elongated elements disposed within the needle may be at least partially disposed within a respective capillary, and each elongated element is capable of movement from a first retracted configuration within the needle to a second extended configuration outside the needle from each respective hole, wherein the distal ends of the elongated elements are farther apart from each other in the extended configuration than in the retracted configuration. At least one of the plurality

of elongated elements can be an electrode, wherein each capillary is electrically insulated from the series of interior capillaries.

[0006] Also disclosed is a method of infusing a solution into a treatment area including percutaneously inserting into the treatment area a needle having at least two holes along a side of the needle, injecting a treatment solution through the needle into the treatment area with sufficient pressure to infuse the solution between at least one fibrous structure and at least one chamber of adipose tissue. The needle may be at least partially withdrawn prior to injecting the treatment solution.

[0007] At least two tines may be extended through the shaft of the needle and through the at least two holes so that each of the tines disrupts at least one tissue outside the needle in the treatment area. The method further comprises at least partially retracting the at least two tines back into the shaft of the needle.

[0008] In some aspects, the shaft comprises multiple capillaries traversing a length of the shaft, each capillary terminating at a respective output port, wherein the holes along the side of the needle is represented by respective output ports. The method further comprises extending the at least two tines through the multiple capillaries and respective output ports, so that each of the tines disrupts at least one tissue outside the needle in the treatment area, and then at least partially retracting the each of the at least two tines back into the multiple capillaries.

[0009] Injecting the treatment solution may be timed to a pressure function rectangular in shape with little rise and fall times, whereby the pressure may be delivered at a maximum level for all times during the injection. The method may further comprise

[0010] Injecting a second treatment solution through the needle into the treatment area, and applying an energy source to the treatment area from a source external to the treatment area, wherein the energy source is selected from the group consisting of ultrasound, RF, heat, electricity, or light.

[0011] A group of interleaved functions may be provided including a high-pressure burst, a solution infusion, and a treatment. The group may be performed one or more times. The high pressure burst is represented by injecting the treatment solution and the treatment includes injecting a third solution or applying an energy to the treatment area, and the high pressure burst is timed to a pressure function, the solution infusion is timed to an infusion function, and the treatment is timed to a treatment function, wherein each function is rectangular in shape with little rise and fall times. Alternatively, the high-level burst may be performed first, followed by a group of interleaved functions including the solution infusion and the treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] FIG. 1 depicts the device of the present invention in use in a treatment area.

[0013] FIGS. 2A-2E depict embodiments of the needle of the present invention.

[0014] FIGS. 3A-3C depict the needle with internal capillaries and output ports.

[0015] FIG. 4 depicts the tines of the present invention.

[0016] FIGS. 5A and 5B depict the tines in use in the treatment area.

[0017] FIGS. 6A and 6B depict the high-pressure burst of the present invention.

[0018] FIGS. 7A-7C depict an embodiment of the high pressure burst.

[0019] FIGS. 8A-8B depict an embodiment of the high pressure burst.

[0020] FIG. 9 depicts a high-pressure system configuration.

[0021] FIGS. 10A-10C depict an aspect of the high-pressure system configuration.

[0022] FIGS. 11A and 11B depict the interleaved functions of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] Referring first to FIGS. 1A and 1B, a cross section of a portion of a normal subcutaneous tissue region 100 is shown, including the epidermis 102, dermis 104, subcutaneous fat 106, fibrous septae 108, and deeper fat layers 110. The subcutaneous tissue also includes vascularity, microcirculation, and lymph drainage. The dermis interfaces with the fatty subcutaneous connective tissue that attaches to the dermal layers via substantially vertical septae 108 (collagenous fibers). The subcutaneous fatty tissue 106 is compartmentalized into chambers 112 of adipose tissue (fat) separated by the fibers of the septae. These chambers can increase in size due to the presence of increased adipocytes (fat cells) 114 or swell due to retained fluid. The increase in chamber size may cause tension on the septae and ultimately dimpling at the epidermal surface as the fatty regions swell and the septae thicken under the tension. Microcirculation and lymphatic drainage may then become impaired, further exacerbating the local metabolic pathology. As shown in FIG. 1A, the subcutaneous fat layer is swollen and septae tightened, leading to the irregular skin surface characteristic of cellulite. A reserve or deeper fat layer 110 is disposed beneath the subcutaneous fat 106 and may also contribute to a skin irregularity. The deeper fat layer is also included herein as one of the subcutaneous tissues that may be treated by at least one embodiment of the present invention.

[0024] In one aspect of the invention, treatment of subcutaneous tissue includes disruption of the fibrous septae 108 to lessen the tension on the skin surface 102 that contributes to dimpling. In another aspect, treatment of subcutaneous tissue includes disruption of the subcutaneous fat cells 114. In yet another aspect, treatment of subcutaneous tissue includes disruption of a deeper fat layer 110 for overall surface contouring.

[0025] The needle of the present invention utilizes an elongated needle-type device 200 capable of being inserted into a subdermal treatment area. In some aspects, the tissue to be treated may be injected anywhere between the dermis layer and the deep fat layer. In one aspect the needle may be precisely placed in the subdermal fat, i.e. the shallow fat layer which is between 1 and 20 mm below the dermis or in the deep fat layer which is between X and Y mm below the dermis. According to one aspect, the treatment area 106 is typically located in a subdermal fat layer between 1 mm and 5 mm below a dermis. The needle may be inserted through, or proximal to, one or more fibrous structures 108 responsible for creating a chamber of fat cells 112 in the treatment area, or through or proximal to a group of fat cells 114 in the treatment area. In another aspect, the needle is placed between 5 mm and 20 mm below the dermis. In other aspects, the tissue to be treated may be injected anywhere between the superficial fat

layer and the muscle layer. In yet other aspects, the tissue to be treated may be injected anywhere between the dermal layer and the muscle layer.

[0026] The device 200 has an thin elongated shaft which is configured to be percutaneously inserted through dermis 104 and into the subdermal treatment area. As depicted by FIG. 1A device 200 is preferably inserted in a manner such that it remains parallel to the overall surface of the skin. This may be accomplished by using one hand to depress the skin while inserting the device from a side of the depression such that it can then be percutaneously inserted laterally through the dermis. A second hand (or one or more fingers) may cover the epidermis to stabilize device 200 as it moves within the treatment area parallel to the surface and second hand.

[0027] In an embodiment depicted by FIG. 1B, the insertion device has a flexible portion 202 which allows the device 200 to bend on entry into the treatment area such that it is more easily maneuvered within the treatment area parallel to the surface of epidermis 102. Device 200 is percutaneously inserted into the treatment area and bent slightly so that the distal end having the fluid ports remains parallel to the skin, between the skin and the lower muscle layers below the subcutaneous fat layer. In such embodiment, device 200 may include a flexible portion, or device 200 may be a flexible cannula.

[0028] Device 200 includes a needle 210, or needle 300, which may be attached to a syringe or other fluid delivery system. Needle 210, 300 may be only a portion (preferably the end) of device 200 or may be the equivalent of device 200. Because needle 210, 300 may make up, in some embodiments, the entirety of device 200, needle 210, 300 may also be used sometimes herein synonymously with device 200. Needle 210, 300 is used to inject solution directly into the treatment area described above. Referring to FIGS. 2A through 2E, needle 210 has a single hole or port (not shown) at its distal end, however, needle 210 more preferably has more than one hole or port 204, located along at least one side of needle 210. Multiple ports 204 are used to allow a broader distribution of fluid delivered by device 200 throughout the area of treatment during an injection. The solution will infuse into the subcutaneous tissues, including the subcutaneous fat and adipose tissue. The solution may be infused directly into the fat cells making them larger and more vulnerable to injury and/or infused over a wider distribution of area to be treated.

[0029] In some embodiments, such as depicted in FIGS. 2A, 2B and 2D, the ports 204 may be aligned on a side of device 200 and/or needle 210 so that when device 200 is positioned in the subcutaneous treatment area it can be further oriented such that the infusion occurs predominately in the plane of the fat, parallel to the surface of the skin, ensuring that the fluid is further distributed over the largest possible area. In other embodiments, as depicted in FIGS. 2C and 2E, the ports 204 may be staggered. One particular advantage of a staggered configuration is an increased mechanical strength. Another advantage is the ability to infuse solution throughout the treatment area without necessitating perfect alignment of needle 210. Other scenarios are foreseen where chambers 112 may exist in an at least partially stacked configuration in which infusion in a non-parallel manner may be appropriate to reach the chambers and be effective for treatment.

[0030] Similar to hypodermic needles, the needle 210 is preferably made from a stainless-steel tube drawn through progressively smaller dies to make the needle. The ports can

be drilled after the forming process is completed or, in some cases, created during the forming process by typical progressive die technique, including, for instance, a piercing operation. The needle may also be embedded in a plastic or aluminum or stainless steel hub at its most proximal end to allow attachment to a syringe barrel or other fluid delivery device by means of a press-fit or twist-on fitting. In embodiments incorporating a flexible portion **202** or cannula, device **200** (including the needle) or those flexible portions thereof are preferably made from a flexible material such as plastic or polymeric material, or a polyurethane or polyurethane hybrid co-polymer, sterile silicone, or any material known in the cannula art.

[0031] As depicted by FIG. 2A, the end of needle **210** may be pointed or beveled to create a sharp tip to allow the needle easily penetrate the skin. FIG. 2B depicts an embodiment of needle **210** including a blunt tip **218**. In some instances, a blunt tipped needle **210** may be inserted into a pre-existing opening in the dermis and blunt tip **218** used to break the fibrous structures by blunt dissection. It is understood that by using blunt dissection the surrounding blood vessels are less likely to be severed but will only be stretched and thus the surrounding structures will be less traumatized by not being sharply cut. It is expected that this will result in less trauma to the patient as well as lesser complications during the procedure. In other embodiments, blunt tip **218** is used merely to avoid any cutting of tissue during the injection of the fluid.

[0032] In some embodiments the needle or cannula may include a trocar tip **220** for introduction of the device to the treatment area. This is particularly advantageous in those embodiments where a smaller gauge (e.g., 7 gauge) needle is used, or in embodiments in which the delivery device is a tubular member or a catheter or trocar. The trocar tip can be fashioned at the distal end of the device or it may be passed inside a cannula to function as a portal for the subsequent placement of other devices herein described.

[0033] Turning to FIGS. 3A through 3C, in some aspects device **200** is a needle **300** (incorporated within or in addition to needle **210**) further formed to include of a series of interior capillaries **302** originating at a point near or at the proximal end **304** of the needle shaft with each interior capillary **302** traversing the length of the shaft **306** to terminate at a respective output port **308**. In this embodiment the diameter **310** of needle **300** may be fixed to a slightly larger nominal outer diameter, e.g., 9 to 12 gauge, to accommodate multiple internal capillaries **302** each including a much smaller nominal outer diameter, e.g., 26 to 34 gauge. Larger or smaller sizes of needle **300** and/or interior capillaries **302** may be used depending on the desired properties of the fluid used in the device as well as the tolerance of the ultimate patient and/or skin-type. For example, in one embodiment in which the needle has an outer diameter of 9 gauge (3.7 mm) the needle may have up to 12 interior capillaries each including an outer diameter of 31 gauge (0.26 mm). As depicted in FIG. 3C, the internal capillaries **302** are preferably configured to be grouped in an array about a common axis **314** of the body of device **200**. For ease of manufacture and predictability of delivery, the middle-most capillaries extend to the most distal ends of the needle/device **200**, **300**, with the outer most capillaries **302** terminating at a more proximal location **304**. Referring back to FIG. 3B, in embodiments in which a staggered port configuration is used, the capillaries **302** terminate at respective ports **308** along a side of needle **300**, and respective to the capillary location, and in respect to a common axis

314. In a parallel port configuration the capillaries are further preferably modified to bend to accordingly terminate at a respective parallel port **308**, with the capillaries closest to axis **314** terminating at the most distal ports and the outer-most capillaries terminating at ports at more proximal locations. Additionally, in some embodiments, the interior capillaries may be aligned at their respective ports such that the fluid leaves the port at a specified angle; e.g., 45 degrees.

[0034] In the embodiment depicted by FIGS. 3A through 3C, the needle is preferably formed in two stages. In one stage, the capillary array is formed according to the desired embodiment (e.g. parallel port or staggered port). In a second stage, the needle is formed using the process previously described. In a third stage, the capillary array may be inserted into the needle housing and sealed accordingly about its ports using micro/nano assembly techniques and/or sealed at the cavity between the interior capillaries and inner diameter of the needle housing the capillaries. In an embodiment in which the insertion device includes a flexible cannula, the capillaries will preferably include smaller flexible tubing or cannula-like structures. In this embodiment the forming process is similar, however, a parallel port configuration will typically require less construction effort due to the flexibility of the interior capillaries.

[0035] In practice, if the cavity between the proximal end of the interior capillaries and inner diameter **304** of the needle housing is filled then fluid from the fluid input location at the most proximal end of the needle can be moved with substantially equal force into each capillary and consequently out each respective port **308**. It has been shown that, where microbubbles are part of the modality of the treatment solution, this configuration is particularly advantageous as forcing a fluid through a larger diameter channel (e.g., needle body interior) into a smaller capillary (e.g., each capillary **302**) will increase cavitation downstream at the capillary output port thereby increasing microbubble formation in vivo as the fluid exits from the needle ports.

[0036] In yet a further aspect of the invention, device **200** may be adapted to deploy an array of tines to a subcutaneous region to be treated. Turning to FIG. 4, the array of tines **402** are selected from the group consisting of needles, electrodes, and cutting elements. Suitable tines **402** for practicing the invention are disclosed in U.S. Publication No. 2007/0060989 to Deem et al., filed Sep. 5, 2006, incorporated herein by reference. In one embodiment, each tine is an electrode providing a fanned array of electrodes.

[0037] The tine elements **408** may be deployed through the skin **102**, **104** through the main shaft **306**, each tine within a respective capillary **302**, and "fan out" from each port **308** in an orientation substantially horizontal (parallel) to the skin surface **102** in a parallel port configuration (e.g., FIG. 2A), or fan out around the needle in a staggered port configuration (e.g., FIG. 2C). In embodiments where the tines are also electrodes, the material of device **200** and/or needle **210**, **300** is electrically non-conductive or coated with an insulating coating. This prevents short circuits and heat related effects from occurring in the treatment area when the electrodes are charged in contact with the needle housing, either internally or after deployment of the electrodes. Upon deployment of the tines and application of energy, the subcutaneous structures such as subcutaneous fat **106** or the fibrous septae **108** may be disrupted. By having each capillary electrically insulated each tine may also be positively or negatively charged so as to create a multipolar, bipolar, or monopolar electrode

configuration. In a further embodiment, the needle tip geometry may be configured to shape the energy field for particular tissue disruption effects.

[0038] Using multiple tines, it is possible to treat a greater area in a shorter amount of time. The tines of the electrode device may further be adapted to be hollow to allow injection of treatment enhancing agents. The hollow tines may have further outlet ports (not shown) at the distal end of each tine as well as along the length thereof.

[0039] Referring to FIGS. 3A through 3C, device 200 including needle 300 may have a first (proximal) end 304, a second (distal) end 310 adapted for insertion into subcutaneous tissue, and one or more channels 302 longitudinally disposed therebetween. A plurality of extendable elongated elements 402 may be bundled at a proximal location 404 and second distal ends 408 that may be inserted/disposed within needle 300 and/or at a respective channel 302, and capable of movement from a first retracted configuration within needle 300 to a second extended configuration outside device 300, outward from each respective port 308, wherein the distal ends of the elongated elements 402 are farther apart from each other in the extended configuration than in the retracted configuration. The elements 408 may be inserted into capillaries 302 at a proximal end 304 of needle 300. The needle of the device may or may not include capillaries 302, whereby, in embodiments without such capillaries the elongated elements are disposed in needle housing such that the ends of the elements partially extend out from ports 204 or disposed in a tubular member 300 (e.g., FIG. 5A) having a central channel, wherein the needles are configured for movement between an extended position in which the needles protrude out from the central channel in a fanned configuration and a retracted position in which the needles are fully retracted in the central channel.

[0040] In one embodiment each tine/electrode 408 may be electrically insulated from the other by an insulative coating formed along the length and circumference of each insulated tine 408. The coating can be any insulation known in the art for electrically insulation of wire. The coating preferably will extend beyond bundling location 406 so that a relatively small portion of each respective electrode 408 extending outside needle 300 and port 308 remains exposed for maximum RF density. The array of tines may also be a tubing in which the bundled electrodes and/or tines are disposed, a shaft 410 wherein the bundled wires are retained, shaft 410 having a distal portion 404 whereby the electrodes are bundled, and a proximal portion 412. In one embodiment a connector (not shown) is provided near or at proximal location 412 for connecting each electrode to a energy delivery device such as an RF amplifier (not shown). In a further embodiment, harmonic scalpel elements 408 may be used in the array.

[0041] In yet another embodiment, one or more RF knives may be used in the array. The RF knife applies a high-frequency electric current to biological tissue as a means to cut, coagulate, desiccate, or fulgurate tissue (electrosurgery). In yet another embodiment, mechanical scalpels or cutting elements may be used in the array. The Harmonic scalpel is a cutting instrument used during surgical procedures to simultaneously cut and coagulate tissue. The instrument is capable of cutting through thicker tissue, creates less smoke, and offers good precision. The Harmonic scalpel coagulates as it cuts, and, causes less lateral thermal damage than other tools, such as a RF knife. The Harmonic scalpel cuts via vibration; i.e., the scalpel surface itself cuts through tissue by vibrating

in the range of about 20,000 Hz. This vibration cuts through the tissue and seals it using protein denaturation, rather than heat.

[0042] In yet another embodiment, the tines are merely sharp cutting elements 408 that do not deliver energy, but can be extended to pierce, disrupt and/or destroy fibrous structures 108 and/or chambers 112 and/or cell groups 114 when needle 300 is positioned within the treatment area. In such an embodiment the elements 408 may or may not be insulated, and may be bound together at a junction 404 such that the cutting elements 408 can be easily inserted into capillaries 302 and/or needle 300 at proximal end 304. Shaft 410 may be used to manipulate the elements 408 within device 200. In practice, elements 408 may also be positioned parallel to the skin surface 102 and rotated about the longitudinal axis 314 (FIG. 3C) of needle 300 or retracted in a substantially parallel orientation to the skin, so that needle 300 can efficiently disrupt multiple septae 108 in one rotation or retraction. In still another embodiment device 200 can be adapted for infusion of treatment enhancing agents into the treatment area through channels 302 and ports 308. In such embodiments the tines may be extended to create canals in tissue through which a solution from device 200 can travel.

[0043] Still referring to FIG. 4, in yet a further embodiment, a tine 408, for example, a cutting element may be deployed at an acute angle to the center axis 314 of needle 300. The array of tines 402 can be collapsed for insertion through needle 300, and then expanded once placed in the subcutaneous space 106, 108, 110.

[0044] As depicted in FIGS. 5A and 5B, elements 408 may be employed through the skin 102, 104 through main tubular member or needle 210, 300, and “fan out” in an orientation substantially horizontal (parallel) to the skin surface. In at least one embodiment, upon deployment of the microneedles such that they are substantially parallel to the skin surface, the subcutaneous structures such as the fibrous septae 108 may be disrupted. Using multiple needles, it is possible to treat a greater area in a shorter amount of time. The microneedles may be configured with additional outlet ports (not shown) along the length of the microneedles. In one aspect, the needles include sharp cutting elements.

[0045] When the needles are positioned parallel to the skin surface and inserted into the subdermal treatment area the fanned element array 402 can efficiently disrupt multiple septae 108 in one deployment of elements 408 from needle 300 (e.g., FIGS. 3B and 4). In another aspect, when the needle 300 including elements 408 is rotated 501 about the axis 314 or retracted upwardly towards the epidermis 102, the fanned element array 408 can efficiently disrupt multiple septae 108 in one rotation or retraction. In at least one embodiment, some of the needles may be solid without central channels and one other may have a channel for injection. In one embodiment, at least one needle in the needle array is further configured for delivery of electrical energy through the needle to heat tissue or disrupt tissue. In one embodiment, at least a portion of the needle is electrically insulated, wherein the electrical energy is dispersed to the tissue over only a portion of the needle. The invention may also be combined with subcision procedures and device such as that disclosed in U.S. Pat. No. 6,916,328 to Brett, filed Jul. 22, 2002, and entitled “PERCUTANEOUS CELLULITE REMOVAL SYSTEM,” the entirety of which is incorporated herein by reference. Combination with subcision may be particularly advantageous in areas of severe cellulite pathology. Upon expansion to its cutting configura-

tion, as shown in FIGS. 5A and 5B, the shaft 306 is then oriented parallel to the skin surface 102 and needle 300 is pulled back, catching and cutting the septae 108 in its path. Elements 408 may be, for example, a blunt dissector, a mechanical cutter, or an energy-assisted device. In energy-assisted embodiments, any of the applicable energy modalities may be employed, including radiofrequency energy or resistive heat energy.

[0046] In one embodiment, the fan-type electrode configuration of FIGS. 5A and 5B may be deployed in conjunction with a tissue disruption device (not shown), for example, a compatible electrode or ultrasound. Suitable disruption devices for practicing the invention are disclosed in U.S. Publication Nos. 20070055180 to Deem et al., filed Jan. 17, 2006, 2007/0060989 to Deem et al., filed Sep. 5, 2006, and 2008/0200863 to Chomas et al., filed Jun. 29, 2007, all incorporated herein by reference. The tissue disruption device may be disposed outside the dermis 102, 104. In one embodiment, the fan-type electrodes 402 may be oriented such that the electric field they produce is advantageously positioned to target connective tissue such as the fibrous septae 108. In at least one embodiment the disruption device (not shown) is positively charged and the needle electrodes 408 are negatively charged. One embodiment may include needle 300 as the tissue disruption device and fan-type electrodes 402 may be deployed through the center of needle 300, electrically insulated from the polarized charge of needle 300. In this embodiment channels 302 may be excluded and electrodes 402 may extend out distal end 310. The fan-type electrodes 402 may then be rotated to mechanically assist the energy disruption of the tissue to be treated. In one embodiment the needle electrodes 402, 408 may also be electrically insulated proximally with exposed electrically active distal tips.

[0047] The current invention employs the use of a high-pressure burst of fluid in connection with the injection delivery device (capillary or non-capillary) to improve the extent of fluid distribution and to reduce pooling of fluid in the treatment area along the needle. The high-pressure burst may either be a pre-burst before a standard injection is performed, or may be high pressure burst as a means for delivering the desired fluid. The object of the device and method of the present invention is to inject fluid with a high pressure to create low resistance pathways in the tissue. Preliminary studies in gel phantom show improved separation of gel structure and improved delivery of a dye into the gel. It has also been shown that there is a broader distribution of fluid perpendicular to the needle.

[0048] A high-pressure burst may be employed prior to the injection of treatment solution so that the subsequent treatment solution is more easily infused into the treatment area. The burst solution may be a solution, such as a saline, which allows for the transport of other treatment solutions. Such treatment solutions used with the present invention may include, but are not limited to, anesthetics such as lidocaine, a surfactant, vasoconstrictive agents such as epinephrine, hypotonic saline, potassium, agitated saline, microbubbles, commercially available ultrasound contrast agents, microspheres, adipocytes, fat, autologous tissues (e.g., lysed fat cells to produce clean adipocytes to form a tissue graft to minimize hostile response from the body), PLLA, hydroxyappetite. The high-pressure burst may also be used to infuse adipocyte or other cells with, for example, a hypotonic saline, to increase their cellular diameter. Larger cells are more vulnerable to injury. Infusion may make the cell mem-

branes more susceptible to damage by producing adipocyte swelling that results in an increase in the stress on the cell membrane. Thus, further treatments may be used to disrupt the targeted cells in the treatment area. In one embodiment, a microbubble solution may be infused into the treatment area and an energy source used to cavitate the microbubbles, causing the surrounding vulnerable cells to destruction. A preferred method of cavitation of microbubbles is disclosed in U.S. Publication No. 20070055180 to Deem et al., filed Jan. 17, 2006, incorporated herein by reference. In another embodiment an external energy source may be used to disrupt the targeted cells from a source outside the body or treatment area. Such energy sources may include, but are not limited to, RF energy, ultrasound, vibrational energy, heat, or laser. In one embodiment an electrode may be inserted into the treatment area to deliver the energy directly to, or proximal to, the cells to be treated.

[0049] Referring back to FIGS. 2A through 2E, the hole diameters of holes 204 will preferably be tuned to the equation $\Sigma A_{holes} = A_{needle} \cdot F$, where A_{needle} is the cross-sectional area of the needle, and where F is a nonlinearity factor, $F > 1$, related to the losses due to the edge effects at each port such that $1 \leq F \leq 10$. (F accounts for the nonlinear losses that occur due to fluid molecules bouncing into each other at edges and interfaces.) It is preferable that the device has a sum of areas of its outlet holes that is greater than the area of the needle relevant to the holes. Referring specifically to FIGS. 2D and 2E, in some embodiments, the diameter of the ports will vary to accommodate for the pressure drop along the needle or cannula. In these embodiments, the holes near the distal end of the needle are preferably equal or larger in area than those near the proximal end or hub, such that $A_3 > A_2 > A_1$ where $E A_i \geq A_{needle}$.

[0050] In one embodiment, the burst uses pressures in the range of 1 psi to 200 psi, where the pressure is below that which may cut soft tissue. The saline or other fluid that is delivered during the high-pressure burst is delivered in bolus volumes, preferably ranging from 0.1 mL to 20 mL. An optional stopcock, pinch valve or other control mechanism may be used to separate the high-pressure burst fluid from the standard device fluid. The high-pressure system must be constructed of components that can withstand high pressure without flexing or absorbing pressure to maintain the most efficient transfer of pressure to the jet at the tissue interface. This includes a high-pressure syringe, tubing, stopcock, and any other components helpful in practicing the invention. The components are preferably required to be sterile, and, the components are also preferably disposable and made of any of a variety of plastics. Reusable components may also be used, requiring sterilization prior to use with each patient.

[0051] FIG. 6A depicts a scenario in which a solution is delivered into the treatment area via a typical needle configuration. The solution, confined by surrounding tissue and fiber septae, is confined to a limited area, with minimal, if any, diffusion of the solution into adjoining chambers of adipose tissue. In the method of the present invention, a saline solution is pre-injected through needle 200 at a high pressure, after which the standard delivery of fluid is performed. As depicted by FIG. 6B the high pressure burst creates low resistance pathways in the tissue along the walls created by the fibrous structures of the subdermal treatment area and allows subsequent fluid delivery to reach a wider area. In an embodiment including a needle or cannula with multiple ports 204, 308 (FIGS. 2A through 2E, and/or 3A through 3C) the burst is

performed along the ports at sufficient pressure to create multiple congruent low-resistance pathways in the treatment area along the fibrous structures therein.

[0052] FIGS. 7A through 7C depict a virtual soaker operation whereby the needle is deployed into the treatment area only to be subsequently retracted creating a cavity within the treatment area including disrupted fibrous septae and/or fat cells and/or chambers of fat cells. The pre-injection burst is then performed into the open channel formed from the cavity to achieve a larger network of pathways and an even more extensive distribution of fluid. In one aspect, the needle is deployed in the tissue, a high pressure burst of saline or other inert fluid is injected, followed by a single or series of injections as part of the medical device operation. In a second aspect, a needle is deployed and then retracted before performing the high pressure burst and low-pressure fluid delivery.

[0053] Device 200 is deployed into the soft tissue by percutaneous injection (e.g., FIGS. 1A and 1B). The needle or cannula may be a medical beveled tip, trocar tip, rounded, square or any other needle tip. The needle may optionally require a second needle or introducer to pierce the skin, or the needle may itself pierce the skin. The high-pressure system may be driven by either pneumatic control, hydraulic control, or electrical motor control. The orientation and direction of the water jets may be manually or automatically controlled (e.g., by ports 204, 308). The jets may emanate perpendicularly to the needle, parallel to the needle (from the tip of the needle) or any angle between.

[0054] As depicted by FIGS. 8A through 8D, device 200 may be deployed with tines/electrodes 402 to practice the burst of the present invention. As depicted by FIG. 8A, needle 210, 300 is first percutaneously inserted into the treatment area. Once in place, as depicted by FIG. 8B, array 402 of elements 408 are then deployed through ports 308 (e.g., FIG. 3B) such that each element 408 is extended to pierce, disrupt and/or destroy fibrous structures 108 and/or chambers 112 and/or cell groups 114, thereby opening multiple fluid channels through the tissue, fat cells, and fibrous structures in the treatment area. Ports 308 are preferably configured such that when elements 408 are extended outward beyond the circumference of needle 300 elements 408 extend outward in a direction parallel to the surface of the skin 102. This maintains pressure within the treatment area and prevents damage to the outer layer of the dermis during treatment. Elements 408 are subsequently retracted, as depicted by FIG. 8C, to provide for greater permeability of the injected solution to the area. It is not necessary that elements 408 are first removed, so long as the fluid remains pressurized throughout device 200 with pressure at each port 308 being substantially uniform. In one embodiment uniform pressure is achieved by tuning the port diameters consistent with the above equation. In one embodiment incorporating needle 300 including capillaries 302 uniform pressure is achieved by applying a pressurized fluid at junction 304, at an even rate, such that the solution is dispersed evenly by each capillary 302.

[0055] FIG. 9 depicts device 200 used in conjunction with a pneumatic drive. A pneumatic drive system 900 may be used to practice the above method to provide pressurization and infusion of solution and/or medication into the treatment area. In one exemplary embodiment, a sterile syringe 902 is fastened to a pressurized line 904 at its proximal-driving end 906. The syringe 902 with the high-pressure driver 906 includes a high-pressure system 908. Pressurized line 904 is

pressurized by a pneumatic piston 910 which in-turn is driven by a compressor 912. Compressor 912 may be any compressor system known in the art, for instance, but not limited to, air, hydraulic, or CO₂ canister. In one embodiment a sensor 914 is disposed at the compressor output to provide for automatic shut-off if the pressure exceeds a predetermined limit. Compressor 912 may further include a reservoir 916 and a regulator 918 to provide proper delivery of the pneumatic driving force. Reservoir 916 and regulator 918 may be any reservoir and regulator known in the art. The compressor system drives piston 910 to in-turn drive high-pressure system 908 to deliver the high-pressure burst of the present invention.

[0056] As depicted by FIGS. 10A through 10C, a fluid control device isolates a delivery device 1006 (e.g., needle or other delivery handpiece) from the fluid infusion system 1002 and the high-pressure system 1004. The fluid control device may be a stopcock 1008 (FIG. 10A), one-way valve 1010 (FIG. 10B), pinch valve 1012 (FIG. 10C), or other fluid control device capable of separating the high pressure fluid system 1004 from the standard device flow system 1002 in the case that the standard device fluid does not tolerate high pressures or is negatively impacted by a high pressure impulse to the fluid. A stopcock, pinch valve, or other fluid control device such as check valves or one-way valves may be used in conjunction with the syringes 1002 so that after a burst, when the driving piston of the system is retracted, a fresh volume of fluid is drawn into the syringe chamber.

[0057] In some embodiments the high-pressure burst will be used in conjunction with infusion of a pre-treatment solution, followed by some other subsequent treatment. The treatment may be the application of an energy source to the pre-treatment solution, or, in some embodiments, may be the application or further infusion of a treatment solution to the treatment area. In either case, the treatment process may be interleaved such that, as depicted by FIGS. 11A and 11B, the steps of infusion and treatment follow the high-pressure burst. The interleaving of the treatment process may be controlled or coordinated by a microprocessor or computer system or may be mechanically or manually interleaved, depending on the condition to be treated and the means available to the treating physician or technician. FIG. 11A depicts the process of interleaving the infusion and treatment whereby a high pressure burst is initiated into the treatment area followed by an immediate infusion into the treatment area. In the preferred embodiment the pressure function is rectangular in shape, with little rise time and fall time so that the maximum pressure is delivered for at all times during the burst. On completion of the infusion (on the fall of the infusion function), the treatment function is initiated, followed by one or more iterations of infusion and treatment. FIG. 11B depicts the process of interleaving the high pressure burst, infusion, and treatment. A high-pressure burst is performed followed by infusion followed by treatment. In one aspect, the steps depicted by FIGS. 11A and/or 11B are repeated one or more times. In the embodiments it is not necessary that each step of burst, infusion, and treatment immediately follow the preceding step. It is possible to program or initiate a delay between selected steps according to a treatment plan.

[0058] The forgoing description for the preferred embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Many modifications and variations are possible in light of the above

teaching. For example, it is possible to combine the various embodiments, the aspects thereof, and the equivalents thereof to achieve the objective of the present invention. It is intended that the scope of the invention not be limited by this detailed description, but by the claims and the equivalents to the claims appended hereto.

[0059] Although the present invention has been described in detail with regard to the preferred embodiments and drawings thereof, it should be apparent to those of ordinary skill in the art that various adaptations and modifications of the present invention may be accomplished without departing from the spirit and the scope of the invention. Accordingly, it is to be understood that the detailed description and the accompanying drawings as set forth hereinabove are not intended to limit the breadth of the present invention.

We claim:

1. A device, comprising:
 - a hollow needle having a lumen and at least two injection ports through an outer surface of the needle and in fluid connection with the lumen; and
 - wherein the ports increase in diameter toward a distal end of the needle, wherein the ports toward the distal end of the needle have a larger area A_i than those near a proximal end, such that $A_3 > A_2 > A_1$.
2. The device of claim 1, wherein $\Sigma A_i \geq A_{needle}$, and wherein A_{needle} is the cross-sectional area of the needle.
3. The device of claim 1, wherein a sum of areas of the ports are greater than an area of a needle surface comprising the ports.
4. The device of claim 1, wherein the ports are staggered.
5. The device of claim 1, wherein the ports are linearly disposed along the outer surface of the needle.
6. The device of claim 1, wherein the device or the needle is flexible.
7. The device of claim 1, further comprising:
 - a plurality of elongated elements disposed within the needle and capable of movement from a first retracted configuration within the needle to a second extended configuration outside the needle from each respective hole, wherein the distal ends of the elongated elements are farther apart from each other in the extended configuration than in the retracted configuration.
8. The device of claim 7 wherein at least one of the plurality of elongated elements is an electrode, and wherein each electrode is at least partially electrically insulated from the other elongated elements.
9. The device of claim 7 wherein at least one of the plurality of elongated elements is one of a cutting element and a harmonic scalpel.
10. A device, comprising:
 - a needle having at least two ports through an outer surface of the needle; and
 - the needle comprising of a series of interior capillaries originating at a point proximal an end of a needle shaft, wherein each interior capillary traverses a length of the shaft to terminate at a respective port.
11. The device of claim 10, further comprising:
 - a plurality of elongated elements disposed within the needle, wherein each elongated element being at least partially disposed within a respective capillary, and
 - wherein each elongated element being capable of movement from a first retracted configuration within a respective internal capillary to a second extended configuration outside the needle from each respective port; and

wherein the distal ends of the elongated elements are farther apart from each other in the extended configuration than in the retracted configuration.

12. The device of claim 11, wherein at least one of the plurality of elongated elements is an electrode, and wherein each capillary is electrically insulated from at least one other capillary in the series of interior capillaries.

13. The device of claim 11, wherein at least one of the plurality of elongated elements is one of a cutting element or a harmonic scalpel.

14. A device, comprising:

- a hollow needle having a lumen and at least two ports through an outer surface of the needle and in fluid connection with the lumen; and
- a plurality of elongated elements disposed within the needle and capable of movement from a first retracted configuration within the needle to a second extended configuration outside the needle from each respective hole, wherein the distal ends of the elongated elements are farther apart from each other in the extended configuration than in the retracted configuration; and
- an elongate control rod extending through the needle lumen and operably connected to the proximal end of each of the plurality of elongated elements such that movement of the control rod causes the elongated elements to move between the extended position and the retracted position.

15. The device of claim 14, further comprising:

- wherein the ports are spaced along the surface of the needle such that a first selected port is relatively closer to a distal end of the needle than a second selected port, wherein the ports toward the distal end of the needle have a larger area A_i than those near a proximal end, such that $A_3 > A_2 > A_1$.

16. The device of claim 14, wherein a sum of areas of the ports are greater than an area of a needle surface comprising the ports.

17. The device of claim 14, wherein the ports are staggered.

18. The device of claim 14, wherein the ports are linearly disposed along the outer surface of the needle.

19. The device of claim 14 wherein at least one of the plurality of elongated elements is an electrode, and wherein each electrode is at least partially electrically insulated from the other elongated elements.

20. The device of claim 14 wherein at least one of the plurality of elongated elements is one of a cutting element and a harmonic scalpel.

21. A method of infusing a solution into a treatment area using a needle having at least two injection ports, comprising:

- percutaneously inserting the needle into the treatment area; and

injecting a treatment solution through the at least two ports into the treatment area with sufficient pressure to infuse the solution between at least one fibrous structure and at least one chamber of adipose tissue.

22. The method of claim 21, further comprising:

at least partially withdrawing the needle prior to injecting the treatment solution.

23. The method of claim 21, further comprising:

extending at least two times through a shaft of the needle and through the at least two ports so that each of the times disrupts at least one tissue outside the needle in the treatment area; and

at least partially retracting the at least two tines back into the shaft of the needle.

24. The method of claim **21**, wherein a shaft of the needle comprises multiple capillaries traversing a length of the shaft, each capillary terminating at a respective output port, wherein the ports are represented by respective output ports, the method further comprising:

extending at least two tines through the multiple capillaries and respective output ports so that each of the tines disrupts at least one tissue outside the needle in the treatment area; and

at least partially retracting the each of the at least two tines back into the multiple capillaries.

25. The method of claim **21**, wherein injecting the treatment solution is timed to a pressure function rectangular in shape with little rise and fall times, further comprising:

delivering the pressure at a maximum level for all times during the injection according to the pressure function.

26. The method of claim **21**, further comprising:

injecting a second treatment solution through the needle into the treatment area.

27. The method of claim **21**, further comprising:

applying an energy source to the treatment area from a source external to the treatment area, wherein the energy source is selected from the group consisting of ultrasound, RF, heat, electricity, laser, or ultraviolet light.

28. The method of claim **21**, further comprising:

providing a group of interleaved functions including a high pressure burst, a second solution infusion, and a treatment; and

performing the group of interleaved functions one or more times;

wherein the high-pressure burst is represented by injecting the treatment solution, and the treatment includes injecting a third solution or applying an energy to the treatment area;

wherein the high pressure burst is timed to a pressure function, the second solution infusion is timed to an infusion function, and the treatment is timed to a treatment function; and

wherein each function is rectangular in shape with little rise and fall times.

29. The method of claim **21**, further comprising:

performing a high level burst in the treatment area, wherein the high pressure burst is represented by injecting the treatment solution and timed to a pressure function;

providing a group of interleaved functions including a second solution infusion and a treatment, wherein the second solution infusion is timed to an infusion function, and the treatment is timed to a treatment function, and wherein the treatment includes injecting a third solution or applying an energy to the treatment area; and

performing the group of interleaved functions one or more times, wherein each function is rectangular in shape with little rise and fall times.

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[标]申请(专利权)人(译)	凸圆形美学		
申请(专利权)人(译)	凸圆形美学，INC.		
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摘要(译)

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